In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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MERDENA MONTGOMERY,	*	
	*	No. 15-1037V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: May 21, 2019
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement, Tdap vaccine, HPV vaccine,
	*	Guillain-Barré syndrome, B12 deficiency,
Respondent.	*	bench ruling
* *		

Michael G. McLaren & Christopher J. Webb, Black McLaren, et al., PC, Memphis, TN, for petitioner;
Robert P. Coleman, III, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

A hearing was held on May 14-15, 2019. After the parties submitted all their evidence, the undersigned issued a bench decision, finding that Ms. Montgomery had failed to establish that she was entitled to compensation. See Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 704 n.18 (2008) (noting "[e]ven a special master's ruling on entitlement may be delivered from the bench, with no written opinion").

The undersigned is issuing this document for two reasons. First, if only a bench decision was issued, the public would not have access to the transcript containing the bench decision and, thereby, the reasoning underlying the decision. To allow public access to the reasoning underlying the decision, this document will become available to the public pursuant to 42 U.S.C. § 300aa-12(d)(4).

Second, this document provides an abbreviated recitation of the basis for decision. See Hebern v. United States, 54 Fed. Cl. 548 (2002) (example of a judge from the United States

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website (https://www.uscfc.uscourts.gov/aggregator/sources/7). This posting means that the decision will be available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Court of Federal Claims formalizing a bench ruling denying a motion for review). The undersigned's consideration of the evidence began when the evidence was received. See Vaccine Rule 5. As explained in the decision from the bench, the undersigned considered all the evidence, including the medical records, expert reports, medical articles, and oral testimony.

Facts

The parties agreed that medical records created contemporaneously with the events described in the records mostly set forth events in Ms. Montgomery's life accurately. Moreover, because the parties' briefs are generally in agreement on the facts, only a succinct recitation of facts is presented here. The bench decision contained a more detailed presentation of the relevant facts.

Prior to the vaccinations, Ms. Montgomery did not enjoy perfect health. She had chronic lower back pain from a car accident in 2001 and also suffered from neck pain, depression anxiety, obesity, gastroesophageal reflux disease, irritable bowel syndrome, hypertension, and B12 deficiency. Exhibit 2 at 24; exhibit 4 at 130.

On January 28, 2013, Ms. Montgomery received the tetanus-diphtheria-acellular pertussis ("Tdap") and human papillomavirus ("HPV") vaccinations. Exhibit 2 at 4, exhibit 3 at 5. According to Ms. Montgomery's testimony, on approximately February 7, 2013, she began to experience numbness. This numbness began in her right arm, near her forearm. On February 25, 2013, Ms. Montgomery saw her primary care physician, Dr. Zulueta, complaining of the pre-existing conditions noted above and left arm pain. Exhibit 4 at 130. In his assessment, Dr. Zulueta noted "numb tongue/arms/feet ?neuropathy" and ordered B12 testing. Id. at 132, 200 (B12 test results). At a March 4, 2013 appointment with Dr. Zulueta, Ms. Montgomery complained of numbness all over her body for one week and falling the previous day due to an unsteady gait. Id. at 127. Dr. Zulueta reiterated his assessment of "numb tongue/arms/feet ?neuropathy" and also stated "B12 low end of normal." Id. at 128. Dr. Zulueta planned to refer Ms. Montgomery to a neurologist. Id. at 129.

From a later notation during physical therapy, it appears that Ms. Montgomery started using a walker on March 16, 2013. Exhibit 5c at 23. In the morning of March 20, 2013, Ms. Montgomery saw her neurologist, Dr. Krishnaswamy, for the first time after vaccination. Ms. Montgomery complained of numbness of her entire body for one month and an unsteady gait. Exhibit 14 at 6.[2] Dr. Krishnaswamy diagnosed Ms. Montgomery with Guillain-Barré syndrome ("GBS") and directed her to go to the hospital. Id. at 7. On the same day, Ms. Montgomery was admitted to the hospital and treated for the GBS diagnosis with IVIG but a B12 deficiency was also noted and treated. Exhibit 5 at 112. During her five-day hospitalization, Ms. Montgomery was seen by other medical professionals who continued treating her with IVIG for GBS and also

[2] The parties disputed Dr. Krishnaswamy's notation regarding Ms. Montgomery's reflexes. Ms. Montgomery, supported by an explanatory letter from Dr. Krishnaswamy (exhibit 51), argued that the circle notation over the 2+ for Ms. Montgomery's reflexes indicated a zero, meaning no reflexes. The Secretary argued that the circle notation was actually an emphasis of the 2+ indicating that Ms. Montgomery had normal reflexes.

treating a B12 deficiency. Id. at 69, 114, 116, 118, 127. Ms. Montgomery's discharge summary noted she "had improvement in overall symptoms" and included diagnoses for GBS and B12 deficiency. Id. at 110.

Throughout the medical records created in February and March 2013, there are inconsistencies and sometimes contradictions within the same entries about what symptoms, notably weakness and numbness, Ms. Montgomery was experiencing. These inconsistences and contradictions within the medical records have made it difficult to come to conclusions on different factual issues.[3]

Following her hospitalization, Ms. Montgomery has made a partial recovery but still has limitations on her activities requiring help from others. The parties agree that the medical records after this key hospitalization in 2013 do not bear on the issue of establishing causation.

Procedural History

Ms. Montgomery alleged that the Tdap and HPV vaccines caused her to develop GBS. Pet., filed Sept. 17, 2015. Ms. Montgomery finished the submission of her medical records and filed a statement of completion on October 26, 2015.

The Secretary filed his Rule 4 report on February 16, 2016. In the report, he disputed Ms. Montgomery's GBS diagnosis and, even if he accepted the diagnosis, he argued that no treating physicians had connected the vaccinations to Ms. Montgomery's injuries nor had Ms. Montgomery offered a medical theory to explain how the vaccines caused her injuries. The case then proceeded to the expert report phase with instructions regarding expert reports issuing on November 21, 2016. The instructions advised the parties that the expert reports may constitute direct testimony and, accordingly, any direct testimony by the experts at a hearing would be limited.

On February 15, 2017, Ms. Montgomery filed her first expert report from Dr. Lawrence Steinman. Dr. Steinman accepted the GBS diagnosis from Dr. Kishnaswamy and offered a medical theory that the HPV vaccination caused Ms. Montgomery's GBS via molecular mimicry and the alum adjuvant in both vaccinations caused her GBS. Exhibit 17 at 7-18.

On November 17, 2017, the Secretary filed expert reports from Dr. Lindsay Whitton and Dr. Peter Donofrio. Dr. Whitton's report argued against Dr. Steinman's medical theories (exhibit A) and Dr. Donofrio disputed Ms. Montgomery's GBS diagnosis (exhibit Z). Dr.

[3] Because the ultimate outcome does not depend on whether Ms. Montgomery established, by preponderant evidence, that she suffered from GBS, further evidentiary development is not required. In particular, the undersigned's decision did not need to wait for Ms. Montgomery to obtain transcriptions of notes a neurologist (most likely, Dr. Krishnaswamy) made during her hospitalization. While the handwriting is difficult to understand, during the hearing, Dr. Steinman and Dr. Donofrio could interpret most of the entries. Regardless of some limitations on the legibility of the notes, the entries clearly show that the author was assessing Ms. Montgomery as suffering from GBS. See exhibit 5b at, inter alia, 117, 124, 126, 135.

Donofrio offered the alternative diagnoses of hypothyroidism and B12 deficiency. Exhibit Z at 6.

On February 21, 2018, Ms. Montgomery filed a second report from Dr. Steinman (exhibit 43). The Secretary then filed responsive reports from Dr. Whitton (exhibit FF) and Dr. Donofrio (exhibit JJ). After the close of the expert reports phase, an entitlement hearing was set for May 2019.

On November 20, 2018, the undersigned issued an order setting a briefing schedule and outlining the requirements for the briefs. After four months, Ms. Montgomery filed her brief on March 9, 2019, and the Secretary filed his on April 9, 2019. The undersigned found the briefs, particularly Ms. Montgomery's brief, to lack substance and a full articulation of the parties' positions. A revised set of briefs were ordered and the parties were warned that deficient briefing could endanger the entitlement hearing from being held. Order, issued Apr. 15, 2019. Ms. Montgomery then filed an improved revised brief on April 29, 2019, and the Secretary filed a revised brief on May 8, 2019.

The entitlement hearing was held on May 14-15, 2019. The witnesses were Ms. Montgomery, Dr. Steinman, Dr. Whitton, and Dr. Donofrio. At the close of evidence, the undersigned issued a bench decision denying compensation for Ms. Montgomery.

Analysis

Ms. Montgomery bears the burden to establish her case on a more-likely-than-not basis. 42 U.S.C. § 300aa-13(a); Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). The elements are set out in Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

While establishing a diagnosis is also required, see Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339 (Fed. Cir. 2010), the undersigned does not make a finding on diagnosis for the reasons that follow. The Secretary opposed Ms. Montgomery's GBS diagnosis. Dr. Donofrio described the typical presentation of GBS as "numbness and tingling in the toes that ascends to the legs over a few days, moves to the hands and arms, and later, or at the same time, weakness begins in the arms and legs." Exhibit Z at 5. At the hearing, Dr. Donofrio also emphasized that the typical progression of GBS was bilateral and symmetrical. Ms. Montgomery did not present as expected. Ms. Montgomery testified that she first felt numbness in one arm and then her tongue. Dr. Steinman did not necessarily dispute the diagnostic criteria proposed by Dr. Donofrio but instead maintained that the facts from the medical history could satisfy the diagnostic criteria for GBS.

In his discussion of the diagnostic criteria for GBS, Dr. Donofrio went into more detail than Dr. Steinman and added the expected nadir of GBS symptoms. Resp't's Rev. Post-H'rg Br., filed May 8, 2019, at 9. One of the Secretary's proposed diagnostic criteria for GBS was a "monophasic illness pattern AND interval between onset and nadir of weakness between 12h and

28 days AND subsequent clinical plateau." Id. (citing exhibit BB[4] at 1). Dr. Donofrio testified that 90% of GBS cases reach a nadir within 28 days after onset. Exhibit Z at 5. At the hearing, Dr. Steinman agreed that the nadir for most cases of GBS occur by 28 days. The parties do not dispute that Ms. Montgomery's March 20, 2013 hospitalization was the nadir of her neurologic symptoms. As noted above, Ms. Montgomery's medical records are not wholly clear on when her relevant neurologic symptoms began. If Ms. Montgomery started having neurologic problems on approximately February 7, 2013, which is the date she proposed in her testimony, then the progression of symptoms until the nadir on March 20, 2013 took much longer than expected. Her progression of symptoms calls into question the accuracy of the GBS diagnosis.

In addition to challenging Dr. Krishnaswamy's diagnosis of GBS, Dr. Donofrio proffered a B12 deficiency diagnosis due to Ms. Montgomery's low-normal levels of B12 during the key events and to her neurologic symptoms, including total body numbness. Exhibit Z at 6. However, Dr. Donofrio noted that a critical diagnostic test for B12 deficiency was not conducted to confirm a B12 deficiency diagnosis. Id. While looking at medical records for another reason during the hearing, Dr. Donofrio noted for the first time that Ms. Montgomery had been taking omeprazole for her irritable bowel syndrome. Ex. 2 at 24. Dr. Donofrio testified that B12 deficiency is a possible side effect of omeprazole. Dr. Steinman agreed that omeprazole can cause B12 deficiency.

As noted above, the inconsistent and incongruent notations in the medical records regarding Ms. Montgomery's weakness make her diagnosis uncertain. The records seem to frustrate a clear understanding of when Ms. Montgomery was experiencing weakness and what the overall pattern of that weakness was. However, at this time, it is not necessary to determine diagnosis because this case can be resolved without determining a diagnosis. For the sake of evaluating the Althen prongs, a diagnosis of GBS is presumed.

Althen prong 1 – Medical Theory

Ms. Montgomery has failed to establish a persuasive medical theory by a preponderance of the evidence. Dr. Steinman presented two medical theories: (1) a molecular mimicry theory connecting GBS to the HPV vaccination; and (2) an alum adjuvant theory connecting GBS to the Tdap and HPV vaccinations. The majority of Dr. Steinman's reports and testimony at the hearing was devoted to the molecular mimicry theory.

While Ms. Montgomery does not need to present epidemiological evidence to prevail, the undersigned may consider epidemiological evidence. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1149 (Fed. Cir. 1992) ("epidemiological studies are probative medical evidence relevant to causation"); D'Tiole v. Sec'y of Health & Human Servs., 726 F. App'x 809, 811 (Fed. Cir. 2018) (special masters are not required to "ignore probative epidemiological evidence that undermines petitioner's theory").

Here, regardless of the theory, epidemiological evidence did not support a finding that the HPV vaccine increases the incidence of GBS. Dr. Whitton presented three epidemiological

[4] Exhibit BB: Asbury et al., Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome, 27 (supp.) Ann. Neurol. S21-S24 (1990).

studies on the HPV vaccine and GBS. Exhibit A at 5. In the Gee study, the authors evaluated over 600,000 doses of the HPV vaccine and did not find a statistically significant increase in GBS.[5] In the Chao study, the authors followed almost 190,000 people for 180 days following the HPV vaccination and did not find any cases of GBS.[6] In the recent Vichnin study, the authors again did not find an increased incidence of GBS following HPV vaccination.[7] These studies all examined the HPV vaccine and GBS specifically and did not find a connection between the HPV vaccine and GBS. While these studies are not dispositive, the undersigned views the epidemiological evidence as weighing against Ms. Montgomery's theory that the HPV vaccine can cause GBS. Although the epidemiological evidence undermines much of Ms. Montgomery's evidence on prong one, Ms. Montgomery's theories suffered from other deficiencies as well.

Dr. Steinman opined that the HPV vaccine and the body's myelin basic protein ("MBP") share a homology, a similar sequence, that deceives the immune system into attacking MBP and causing GBS. Dr. Steinman used BLAST, a program that compares nucleotide and protein sequences, to search for a homology between the HPV vaccine and MBP. Dr. Whitton persuasively critiqued Dr. Steinman's overreaching conclusions from BLAST searches and his choice of MBP as the appropriate molecule related to GBS for comparison with the HPV vaccine. Dr. Whitton explained that BLAST searches are appropriate for determining homology between molecules but not for determining cross-reactivity, which is necessary to generate an immune response. Beyond the limitations of BLAST searches, Dr. Whitton also argued that neurologists currently think gangliosides, not MBP, are the target in GBS. While Dr. Steinman admitted the current thought had turned toward gangliosides, he contended that the older literature promoting a connection between MBP and GBS has not been refuted. Because gangliosides are carbohydrates, Dr. Steinman could not conduct a BLAST search on them to determine their homology with the HPV vaccine. The uncertainty on the relevancy of MBP for the development of GBS does not help support Dr. Steinman's theory. Moreover, because BLAST searches do not provide any insight into cross-reactivity, they do little to substantiate Dr. Steinman's theory.

Dr. Steinman presented a second, less-developed theory that the alum adjuvant in the Tdap and HPV vaccines triggered an immune reaction in Ms. Montgomery that caused her to develop GBS. Dr. Steinman argued that the alum adjuvant could induce a cytokine response in the body and that these cytokines are related to the development of GBS. Dr. Whitton persuasively disputed this theory by pointing out that (1) Dr. Steinman did not support how large of a cytokine response is triggered by alum and (2) he did not explain how long the cytokine response lasts. Dr. Whitton explained that duration is especially important here because a release of cytokines is part of the innate immune system's response, i.e., the body's short-term immune

[5] Exhibit N: Gee et al., Monitoring the Safety of Quadrivalent Human Papillomavirus Vaccine: Findings from the Vaccine Safety Datalink, 29 Vaccine 8279-84 (2011).

[6] Exhibit O: Chao et al., Surveillance of Autoimmune Conditions Following Routine Use of Quadrivalent Human Papillomavirus Vaccine, 271 J. Intern. Med. 193-203 (2012).

[7] Exhibit Q: Vichnin et al., An Overview of Quadrivalent Human Papillomavirus Vaccine Safety: 2006 to 2015, 34 Pediatr. Infect. Dis. J. 983-91 (2015).

response. If a cytokine surge caused GBS, then it would be expected that the onset of GBS would be short-term, within one or two days from vaccination. However, in this case, even assuming the earliest onset of numbness on February 7, 2013, that onset is still 10 days after the vaccinations, too long after the vaccinations to implicate the innate immune system and cytokines. Thus, Dr. Steinman's alum adjuvant theory does not fit with Ms. Montgomery's onset. In addition, Dr. Steinman does not provide support for how the cytokine surge in his alum adjuvant theory would be substantial enough to trigger an immune response. See Zumwalt v. Sec'y of Health & Human Servs., No. 16-994V, 2019 WL 1953739, at *18 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (critiquing Dr. Steinman's overly general alum adjuvant theory).

After considering all the evidence, the undersigned finds that Ms. Montgomery has not established the first prong of Althen by a preponderance of the evidence.

Althen Prong 2 - Logical Sequence of Cause and Effect

As a matter of logic, when a petitioner fails to establish that a vaccine can cause a disease (prong one), it follows that the petitioner cannot establish that the vaccine did cause the disease in this specific case (prong two). Nevertheless, the undersigned reviewed the medical records to see if they supported a logical sequence of cause and effect. At the May 9, 2019 pre-hearing status conference, the parties agreed that none of the treating doctors made any statements causally connecting either of the vaccinations to Ms. Montgomery's GBS. Thus, Ms. Montgomery has not met her burden of proof on the second prong of Althen.

Althen Prong 3 - Timing

For the timing prong of Althen, Ms. Montgomery is required to establish the timeframe for which it is medically acceptable to infer causation and when the petitioner's onset of symptoms actually occurred. Shapiro v. Sec'y of Health & Human Servs., No. 99-552V, 2011 WL 1897650, at *13 (Fed. Cl. Spec. Mstr. Apr. 27, 2011) (presenting this two-component articulation of the timing prong), review granted in non-relevant part, decision vacated in part, 101 Fed. Cl. 532 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd per curiam, 503 Fed. Appx. 952 (Fed. Cir. 2013). Dr. Steinman posited that GBS can develop in 42 days following vaccination. Exhibit 17 at 18-19. Dr. Donofrio argued for a shorter timeline for GBS to develop, 28 days. Exhibit Z at 5. As noted by the Secretary in his revised brief, Dr. Donofrio did not address onset because he was disputing the GBS diagnosis. Resp't's Rev. Br. at 16. Without a clear diagnosis, the Secretary did not believe he could address timing. Id. Thus, the Secretary did not dispute that the actual onset of Ms. Montgomery's symptoms were within a viable time frame.

Accordingly, if it is assumed that Ms. Montgomery suffered from GBS and if it is further assumed that her GBS was manifest on February 7, 2013, then Ms. Montgomery satisfied the timing prong. However, an appropriate temporal interval does not mean that Ms. Montgomery is entitled to compensation. See Grant, 956 F.2d at 1148.

* * * * *

Even assuming that Ms. Montgomery established GBS as a diagnosis, Ms. Montgomery failed to meet her burden of showing that the HPV and/or Tdap vaccines can cause GBS. The

undersigned directs the Clerk's Office to enter judgment based upon the decision in this case if a motion for review is not filed. When the time for filing a motion for review (see Vaccine Rule 23) begins to run is for an appellate tribunal to decide.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master